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April 13, 2004

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: U.S. Patent Application No. 09/696,664
Filed: October 25, 2000
Title: **Nucleic Acid Molecules and Other Molecules Associated with Plants**
Applicants: Mark S. ABAD *et al.*
Atty. Docket: 16517.316

Sir:

The following documents are forwarded herewith for appropriate action by the U.S. Patent and Trademark Office (PTO):

1. Appellant's Brief (in triplicate); and
2. a return postcard.

Please stamp the attached postcard with the filing date of these documents and return it to our courier.

Applicants request that the following fee be charged to Deposit Account No. 50-2387 referencing docket number 16517.316:

$ 330.00 Appellant's Brief

In the event that extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned. Applicants do not believe any additional fees are due in conjunction with this filing. However, if any fees under 37 C.F.R. §§ 1.16 or 1.17 are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter Deposit

Account No. 50-2387, referencing matter number 16517.316. A duplicate copy of this letter is enclosed.

Respectfully submitted,

David R. Marsh (Reg. No. 41,408)
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Attachments

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:			
Mark S. ABAD *et al.*		Art Unit:	1631
Appln. No.:	09/696,664	Examiner:	Michael L. BORIN
Filed:	October 25, 2000	Atty. Docket:	16517.316
For:	**Nucleic Acid Molecules and Other Molecules Associated with Plants**	Confirmation No.	5102

APPELLANT'S BRIEF

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

This is an Appeal from the Final Rejection of all claims pending in the above-captioned patent application. A Notice of Appeal was filed on February 13, 2004. Authorization to charge the official fees for this filing is given in the accompanying transmittal letter. *This Brief is submitted in triplicate.*

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

Appellant is unaware of any Appeals or Interferences related to this Appeal.

3. Status of Claims

Claims 1 and 8-13 are pending. Claims 2-7 were cancelled without prejudice to or disclaimer of the subject matter claimed therein in an amendment filed August 15, 2003. Claims 1 and 8-13 stand finally rejected under 35 U.S.C. §§ 101 and 112, first paragraph. Appellant appeals all of the rejections of claims 1 and 8-13.

4. Status of Amendments

Appellant has not filed any responses subsequent to Final Rejection in this case.

5. Summary of Invention

The invention is directed to a substantially purified nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 3. Specification at page 9, lines 24-26. The invention is also directed to a substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 3 or complement thereof. Specification at page 10, lines 1-3. The invention is also directed to a substantially purified nucleic acid molecule comprising a nucleic acid sequence having between 100% and 90% sequence identity with a nucleic acid sequence of SEQ ID NO: 3 or complement thereof. Specification at page 19, line 19 through page 20, line 12.

6. Issues

The issues in this Appeal are:

(a) whether claims 1 and 8-13 are unpatentable under 35 U.S.C. § 101 for allegedly being unsupported by a specific asserted utility or a well established utility;

(b) whether claims 1 and 8-13 are unpatentable under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement because the claimed invention purportedly lacks utility; and

(c) whether claims 1, 8 and 10-13 are unpatentable under 35 U.S.C. §112, first paragraph, for alleged insufficiency of written description.

7. Grouping of Claims

Claims 1 and 8-13 remain in this case. Claims 1, 8 and 10 are independent. All of the claims at issue do not stand or fall together and the separate patentability of claims 1, 8-9 and 10-13 is particularly addressed in Sections 8.B.1.c, 8.D.3 and 8.D.4 below. A copy of the claims on appeal is attached hereto as Appendix A.

8. Argument

A. Summary of Appellant's Position

As the Supreme Court said in *Brenner v. Manson*, the "basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met their part of the bargain – they have disclosed nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example use to identify the presence or absence of a polymorphism in a population of maize plants. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit. Because the claimed nucleic acid molecules provide at least these benefits, they satisfy the utility requirement of 35 U.S.C. § 101. Because the specification teaches how to make and use the claimed nucleic acid molecules for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has been met.

Furthermore, Applicants have provided an adequate description of the claimed nucleic acid molecules that demonstrates Applicants' possession of the claimed invention. The genera of claimed nucleic acid molecules, for example, the genus of nucleic acid molecules comprising the nucleic acid sequence of SEQ ID NO: 3, have

been described by the recitation of common structural features, *e.g.*, the nucleotide sequence of SEQ ID NO: 3, which distinguishes molecules in the claimed genus from molecules not in the claimed genus. Because the specification demonstrates that Applicants had possession of (and have provided an adequate description of) the claimed genera of nucleic acid molecules, the specification satisfies the written description requirement of 35 U.S.C. § 112.

B. The Claimed Nucleic Acids Have Legal Utility

Claims 1 and 8-13 stand rejected under 35 U.S.C. § 101 as allegedly not supported by a "specific, substantial, and credible utility or by a well established utility." Final Action mailed November 13, 2003 ("Final Action"), at page 2. The Examiner has acknowledged that the specification describes multiple utilities for the present invention, including "acquiring genes, identifying polymorphisms, determining plant traits and DNA mapping." *Id.* However, the Final Action asserts these utilities are "an invitation to do further research to search for specific and substantial utility for each polynucleotide claimed." *Id.*

This analysis misstates the nature of the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" developed by the courts after *Brenner v. Manson*. The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip*, 185 F.3d at 1366, 51 USPQ.2d at 1702. For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

Applicants have asserted in the specification that the claimed nucleic acid molecules provide identifiable benefits, for example, use to identify the presence or absence of a polymorphism, and use as a probe for monitoring gene expression. *See, e.g.*, specification at page 40, line 13, through page 48, line 2 and at page 56, line 20, through page 60, line 26. Either of these utilities described alone is enough to satisfy Section 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the premise of the rejection under Section 101 is incorrect, and the rejection should be reversed.

(1) The Claimed Nucleic Acid Molecules Provide A Specific Benefit, *i.e.*, They Have Specific Utility

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including "acquiring genes, identifying polymorphisms, determining plant traits and DNA mapping." *See* Final Action at page 2. Moreover, the

specification also discloses additional utilities for the claimed nucleic acid molecules,[1] including use of the claimed nucleic acid molecules to measure the level of mRNA in a sample,[2] and use as molecular markers,[3] and to acquire promoters. The Examiner argues that such uses are not "considered to be specific and substantial in view of the limited information provided in the specification." *Id.*

(a) Identifying the Presence or Absence of a Polymorphism

More particularly, one of the utilities disclosed in the specification is use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism. Specification at page 40, line 13 through page 48, line 2. The Examiner argues that this utility, like many of the asserted utilities, is not specific or substantial, *see, e.g.,* Final Action at page 2, but does not provide any support (legal or factual) for the proposition that detection of polymorphisms using the claimed nucleic acid molecules is not a legal utility.

Many of the disclosed utilities in this case, including the detection of polymorphisms, are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to locate and measure nucleic acid molecules within

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[1] It is irrelevant whether the corresponding mRNA or polypeptide have utility because Applicants are not relying on utility of the mRNA or polypeptide to establish utility of the claimed nucleic acid molecules.

[2] It is standard practice to screen populations of nucleic acids with EST sequences, often attached to a microarray, without characterizing each and every target mRNA. Knowing that the gene corresponding to the claimed nucleic acid molecules is expressed under certain conditions or in certain tissues or at certain levels is in itself useful. For example, such information is useful to detect expression changes in traits of interest, *e.g.*, plant growth, quality or yield or combinations thereof.

[3] One can use the claimed nucleic acid molecules to determine location of a corresponding DNA sequence on a physical map or genetic map location without knowing anything beyond the claimed sequence. The use of molecular markers is a practical activity in the development of nutritionally enhanced or agriculturally enhanced crops. Such markers are useful in, for example, genetic mapping or linkage analysis, marker-assisted breeding, physical genome mapping, transgenic crop production, crop monitoring diagnostics, and gene identification and isolation. As more markers are identified, genetic maps will become more detailed and it will be easier for plant breeders to breed for particular traits.

a sample, cell, or organism. The Examiner denigrates such utilities by asserting that these utilities are not "useful" because they are non-specific uses. Final Action at pages 2-3. However, the fact that, *e.g.*, a new and nonobvious microscope or screening assay can be used for learning about products or processes does not lessen the fact that such "tools" have legal utility. "Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds)." MPEP § 2107.01 at page 2100-33.

Use of the claimed nucleic acid molecules to detect the presence, absence or identity of polymorphisms is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas – such use determines information about the gas, not the gas chromatograph. Even if the gas chromatograph detects the absence of a particular chemical element in the gas, that finding does not obviate the utility of the gas chromatograph itself. Information has been obtained about the gas.[4] Likewise, the claimed nucleic acid molecules have utility even if the absence of a particular polymorphism is detected. Indeed, the absence of a polymorphism usefully demonstrates that the two (or more) populations being compared share a common genetic heritage.

The claimed nucleic acid molecules have been asserted to work for a specific, *i.e.*, not vague or unknown benefit, to identify the presence or absence of a polymorphism. This benefit is immediately realized directly from the use of the claimed nucleic acids,

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[4] For example, gas sampled from crude oil may be analyzed by gas chromatography for the presence or absence of chlorine, which is toxic to catalysts used in gasoline refining even in very low concentrations. The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine is present, therefore the catalyst will not be destroyed) to the refinery manager. *See, e.g.*, U.S. Patent No. 6,133,740 entitled "Chlorine Specific Gas Chromatographic Detector."

not from the use of other molecules. Such a proven use that provides an acknowledged known benefit to the public satisfies the utility requirement of 35 U.S.C. § 101.

(b) Probes for Other Molecules or Source for Primers

Other uses for the claimed nucleic acid molecules are as probes for other molecules or as a source of primers. The specification discloses that the claimed nucleic acid molecules can be used to isolate nucleic acid molecules of other plants and organisms such as alfalfa, *Arabidopsis*, barley, *Brassica*, soybean, sunflower, *Phaseolus*, etc.[5] Specification at page 22, lines 9-15. The Examiner has not provided any evidence that would reasonably suggest that this cannot be done, and thus has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974).

One illustrative example of a molecule that can be isolated using a claimed nucleic acid molecule is the promoter of the gene corresponding to that claimed nucleic acid molecule. Applicants have specifically disclosed that one use of the claimed nucleic acid molecules is to initiate a chromosome walk. Specification at page 38, lines 5-24. The Examiner suggests that such a utility is not specific. Final Action at pages 2-3. This is not correct. The claimed nucleic acid molecules, isolated from jasmonic acid treated maize leaf tissue, are particularly useful, for example, to isolate promoters responsive to stress in maize leaves. *See, e.g.*, specification at page 34, line 4-25.

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[5] Furthermore, one skilled in the art of hybridization and amplification understands how to design and utilize probes and primers to target a sequence of interest, and therefore it is not necessary for Applicants to provide a laundry list of each and every nucleic acid molecule that can be identified using the claimed nucleic acid molecules. It is not necessary to disclose what is known. *See, Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose, *i.e.,* chromosome walks. That position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result..."). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. That position must be rejected as it requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

Moreover, it is factually incorrect that this use is not "specific" to the claimed nucleic acid molecules. The claimed nucleic acid molecules provide a particularly appropriate and demonstrably useful starting point for a walk to isolate a promoter active in maize plants. *See, e.g.*, specification at page 34, lines 4-25, page 38, lines 5-24 and Example 1 at page 89, line 25, *et. seq*. A random nucleic acid molecule does not provide an equally good starting point to isolate such a promoter. Furthermore, even if a random nucleic acid molecule provided a <u>better</u> starting point than the claimed nucleic acid molecules, it would not obviate the utility of the claimed nucleic acid molecules. An invention may be "less effective than existing devices but nevertheless meet the statutory criteria for patentability." *Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 960 n.12, 1 U.S.P.Q.2d 1196, 1199 n.12 (Fed. Cir. 1986).

The Examiner has failed to provide evidence, or even to suggest a reason for believing that the claimed nucleic acid molecules could not be so used. Accordingly, the assertion of this utility as a probe for other molecules or as a source of primers satisfies

the requirements of 35 U.S.C. § 101. *See In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995).

(c) Claims 8-9 and 10-13 are separately patentable

The Examiner argues that the claimed nucleic acid molecules lack utility apparently because "[o]ne of ordinary skill in the art would have reason to doubt that SEQ ID NO: 3 was full length based upon the short length of the claimed SEQ ID NO." Final Action at page 3. The Examiner additionally argues that "[f]urther research and experimentation would be required to identify a full-length sequence that encoded a full-length protein."[6] The Examiner provides no evidence, however, that the sequence is not full length. Nor has the Examiner provided evidence that a full-length sequence is necessary to use the claimed nucleic acid molecules for the disclosed utilities, for example, as probes, to detect the presence or absence of polymorphisms, and in DNA mapping, all of which the Examiner acknowledges have been asserted in the specification.

As previously stated, the claimed nucleic acid molecules have been asserted to work for a specific, *i.e.*, not vague or unknown benefit, to identify the presence or absence of a polymorphism. This benefit is immediately realized directly from the use of the claimed nucleic acids, not from the use of other molecules. Such a proven use that provides an acknowledged known benefit to the public satisfies the utility requirement of 35 U.S.C. § 101, even if the sequence is not a "full-length" sequence.

[6] Such a basis for rejection, even if valid, would not apply to claims 8-9 and 10-13, which do not recite "a maize protein or fragment thereof."

(2) The Claimed Nucleic Acid Molecules Provide Practical, Real World Benefits, *i.e.*, They Have Substantial Utility

The Final Action also suggests that the disclosed uses are legally insufficient because they are not "substantial" utilities. Final Action at pages 2-3. The touchstone of "substantial" utility is "real world" or "practical utility." *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). " 'Practical utility' is a shorthand way of attributing 'real world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." *Nelson v. Bowler*, 626 F.2d 853, 856, 857, 206 U.S.P.Q. 881, 883 (C.C.P.A. 1980) ("tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use").[7]

There can be no question that one skilled in the art can use the claimed nucleic acid molecules in a manner which provides an immediate benefit to the public, for example to detect the presence or absence of polymorphisms. The detection of polymorphisms provides an immediate benefit to the public because, *e.g.*, it enables a plant breeder to determine the distribution of parental genetic material in the progeny of a cross. This information about a plant's genetic profile, like the information about a compound's pharmacological profile in *Nelson*, provides an immediate benefit and thus a practical utility to the public.

Quite apart from the detection of polymorphisms, there is also no question that the public has recognized the benefits provided by the claimed subject matter, and has attributed "real world" value to such nucleic acid molecules. The utility of ESTs is not merely an academic issue; the real world value of ESTs is self-evident from the growth of

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[7] *Accord Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 U.S.P.Q. 739, 747-48 (Fed. Cir. 1985); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 U.S.P.Q. 453, 454 (C.C.P.A. 1974).

a multi-million dollar industry in the United States premised on the usefulness of ESTs. Like fermentation processes involving bacteria, ESTs and nucleic acid molecules with EST sequences are "industrial product[s] used in an industrial process – a useful or technical art if there ever was one." *In re Bergy*, 563 F.2d 1031, 1038, 195 U.S.P.Q. 344, 350 (C.C.P.A. 1977).

The market participants for EST products are primarily sophisticated corporations and highly knowledgeable scientists who are unlikely to pay for useless inventions. *Cf. Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 U.S.P.Q. 592, 599 (Fed. Cir. 1983) ("People rarely, if ever, appropriate useless inventions"). Quite simply, the commercial value of ESTs is proof of their real world value and of the benefits they provide to the public. This evidence cannot be ignored. The patent system was created to serve and foster growth and development in the industrial arts. If the industries themselves recognize and appreciate the value of an invention, it is not for the Patent Office to say that they are mistaken.

(3) The Disclosed Utilities Are Credible to One of Skill in the Art

An assertion of utility must be accepted by the Examiner unless it would not be considered "credible" by a person of ordinary skill in the art. MPEP § 2107 at 2100-29. Cases in which utility was found not to be credible are rare, and usually involve "hare-brained" utilities.[8] A challenge to the credibility of a utility is essentially a challenge

[8] Examples of incredible utilities are given in MPEP § 2107.01 at page 2100-34, and include:

> an invention asserted to change the taste of food using a magnetic field (*Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 U.S.P.Q. 848 (Fed. Cir. 1985)), a perpetual motion machine (*Newman v. Quigg*, 877 F.2d 1575, 11 U.S.P.Q. 1340 (Fed. Cir. 1989)), a flying machine operating on "flapping or flutter function" (*In re Houghton*, 433 F.2d 820, 167 U.S.P.Q. 687 (C.C.P.A. 1970)), a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field (*In re Ruskin*, 354 F.2d 395, 148 U.S.P.Q. 221 (C.C.P.A. 1966)), uncharacterized compositions for curing a wide array of cancers (*In re Citron*, 325 F.2d 248, 139 U.S.P.Q. 516 (C.C.P.A. 1963)), a method of controlling the aging process (*In re Eltgroth*, 419 F.2d 918, 164 U.S.P.Q. 221 (C.C.P.A.

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directed to operability, and such a challenge must be supported by a clear statement of "factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *see In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); MPEP § 2107.02 at 2100-41.

Applicants have explicitly identified specific and substantial utilities in the specification. "To violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992). To date, the Examiner has provided no evidence that the claimed nucleic acid molecules will not work for the disclosed utilities. Unless and until the Examiner can prove that the claimed invention is wholly inoperative, the rejection must be withdrawn.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claims 1 and 8-13 under 35 U.S.C. §101 is improper and should be reversed.

C. The Claimed Nucleic Acids Are Enabled by the Specification

The enablement of the claimed nucleic acid molecules has been challenged. Claims 1 and 8-13 stand rejected as not enabled by the specification, because the claimed nucleic acid molecules allegedly lack utility and therefore cannot be enabled. Final Action at page 4. This rejection is erroneous and has been overcome by the arguments

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1970)), and a method of restoring hair growth (*In re Ferens*, 417 F.2d 1072, 163 U.S.P.Q. 609 (C.C.P.A. 1969)).

stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

D. The Specification Provides an Adequate Written Description of the Claimed Invention

Despite the Examiner's acknowledgement that the specification discloses the sequence of SEQ ID NO: 3, the adequacy of the written description of claims 1, 8 and 10-13 has been challenged by the Examiner because the claimed subject matter was allegedly "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention." Final Action, at pages 4-5. The basis for the Examiner's challenge is that the 'comprising' language of "the claims encompass gene sequences, encoding sequences and so forth. None of these products meet the written description provision of 35 USC 112, first paragraph as there is no description of other elements included in DNA, such as non-coding regulatory regions, etc." Office Action mailed May 15, 2003, at page 7. This is not a proper basis for a written description rejection of a "comprising" claim. If it was, every "comprising" claim ever written would be invalid for failing to describe every nuance of the claimed invention.

Furthermore, the specification demonstrates to one skilled in the art that Applicants were in possession of the claimed genera of nucleic acid molecules.

(1) The Specification Reflects Applicants' Possession of the Claimed Invention

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if every nuance of the invention was not expressly described, then the written description requirement has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. After reading the present specification, a person of ordinary skill in the art would understand that Applicants had possession of nucleic acid molecules comprising SEQ ID NO: 3, and therefore, the claimed invention.

Applicants have provided the nucleic acid sequence required by the claims, *i.e.*, SEQ ID NO: 3, as well as, for example, vectors comprising the nucleic acid sequence (*see, e.g.,* specification at page 66, line 1 through page 73, line 23), hybridization conditions which may be used with the nucleic acid molecules of the present invention (*see, e.g.,* specification at page 18, line 5 through page 19, line 10), and binary artificial chromosomes (BIBACs) and other systems that may be used to introduce the claimed nucleic acid molecules into a host cell (*see, e.g.,* specification at page 73, lines 18-23). The fact that the claims at issue are intended to cover molecules that include the recited sequence joined with additional sequences does not mean that Applicants were any less

in possession of the claimed nucleic acid molecules.[9] It is well-established that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

Applicants have provided in the present disclosure not only the nucleotide sequence required by the claims (i.e. SEQ ID NO: 3), but also several variations including and directed to the claimed nucleic acid molecules. For example, the present specification describes vectors comprising the claimed nucleic acid molecules (specification at page 66, line 1 through page 73, line 23), and describes how to make the nucleotide sequences and libraries from which they were originally purified. *See, e.g.*, Examples page 89, line 25, *et. seq.* Furthermore, the addition of extra nucleotides or detectable labels to the disclosed nucleotide sequence (SEQ ID NO: 3) is readily envisioned by one of ordinary skill in the art upon reading the present specification,[10] in particular at page 29, line 24 through page 29, line 20 (describing fusion peptide molecules encoded by the claimed nucleic acid molecules), page 17, line 25 through page 18, line 2 (describing sequences with labels to facilitate detection), page 61, lines 16-22 (describing site-directed mutagenesis) and page 85, lines 13-21 (citing references describing the construction, manipulation and isolation of nucleic acid macromolecules).

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[9] If the Examiner is arguing that no possession is shown because the precise claim language is not used in the specification, then he goes beyond what is required by the law. It is well-settled that the description of a claimed invention need not be *in ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972).

[10] It is established patent jurisprudence that Applicants need not teach "conventional and well-known genetic engineering techniques." *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

Moreover, the court determined, in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1321, 63 U.S.P.Q.2d 1609, 1610 (Fed. Cir. 2002), that the written description inquiry is a factual one determined on a case-by-case basis and that, in a given disclosure, "it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of skill in the art." *Enzo*, 296 F.3d at 1326-1327, 63 U.S.P.Q.2d at 1615. Furthermore, it is well established that claims "may be broader than the specific embodiment disclosed in a specification. *Ralston-Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) (*quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981).

(2) Applicants Have Described the Claimed Invention

The Final Action asserts that the "disclosed subgenus and species embraced by the claims are not representative of the entire genus being claimed." Final Action at page 5. The Examiner appears to assert that each nucleic acid molecule within the claimed genus must be described by its complete structure. These assertions are totally unfounded. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicants have satisfied that test for written description.

In particular, Applicants have disclosed structural features, for example, the nucleotide sequences of SEQ ID NO: 3. The respective structural feature (for example, the nucleotide sequences of SEQ ID NO: 3) is shared by every nucleic acid molecule in the claimed genera, and it distinguishes the members of the claimed genera from non-members. For example, if a nucleic acid molecule such as an mRNA contains the nucleotide sequence of SEQ ID NO: 3, then it is a member of the claimed genus of

nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 3.[11] *See*, claim 8. If a nucleic acid molecule does not contain SEQ ID NO: 3, then it is not a member of that claimed genus. The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either contains the nucleotides of SEQ ID NO: 3 or it does not. One skilled in the art, after reading the present specification, would clearly know if a nucleic acid molecule contains the recited nucleotide sequence.

(3) Claims 8 and 10-13 are separately patentable

The Examiner has further rejected the claims as allegedly lacking written description because "[t]he specification does not disclose encoding sequences or open reading frames (ORFs)." Final Action at page 5. However, as has been pointed out, claim 1 is directed to a nucleic acid molecule encoding a maize protein or fragment thereof and the specification discloses that the nucleic acid molecules of the present invention were isolated from maize plants. *Se, e.g.*, specification at page 89, line 26 through page 92, line 13 (Example 1).[12] The Examiner has not presented any evidence to contradict these assertions. Applicants have provided an adequate written description for the claimed invention. That is all that is required.

(4) Claims 1 and 8 are separately patentable

In rejecting Appellant's claims, the Examiner argues that "claims [10-13], drawn to nucleotide sequences having less than 100% identity to the elected SEQ ID 3, does not

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[11] This argument applies with equal force to every genus of the claimed nucleic acid molecule. For example, if a nucleic acid molecule such as an mRNA, comprises a nucleotide sequence having 95% identity to SEQ ID NO: 3, then it is a member of the genus of nucleic acid molecules having 95% identity to SEQ ID NO: 3. *See*, claim 11.

[12] Such a basis for rejection, even if valid, would not apply to claims 8 and 10-13, which do not recite "a maize protein or fragment thereof."

have sufficient description in the specification as description of species is insufficient to support highly variable genus."[13] *See* Final Action at page 6. In relying on this, the Examiner argues that "[t]he effects of changes in the structure are largely unpredictable as to which ones have a significant effect versus not." *Id.* However, this assertion provides no support as to why one skilled in the art would not be able to recognize a nucleic acid molecule comprising the nucleotides of SEQ ID NO: 3.

Thus, claims 1, 8 and 10-13 are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,

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[13] Such basis for a rejection, even if valid, would not apply to claims 1 and 8, which do not recite percentages.

APPENDIX A

1. A substantially purified nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 3.

8. A substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 3 or complement thereof.

9. The substantially purified nucleic acid molecule according to claim 8, wherein said nucleic acid molecule consists of a nucleic acid sequence of SEQ ID NO: 3 or complement thereof.

10. A substantially purified nucleic acid molecule comprising a nucleic acid sequence having between 100% and 90% sequence identity with a nucleic acid sequence of SEQ ID NO: 3 or complement thereof.

11. The substantially purified nucleic acid molecule of claim 10, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 95% and 100% sequence identity with a nucleic acid sequence of SEQ ID NO: 3 or complement thereof.

12. The substantially purified nucleic acid molecule of claim 11, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 98% sequence identity with a nucleic acid sequence of SEQ ID NO: 3 or complement thereof.

13. The substantially purified nucleic acid molecule of claim 12, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 99% and 100% sequence identity with a nucleic acid sequence of SEQ ID NO: 3 or complement thereof.